NOV - 4 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Submitter: Irvine Biomedical, Inc.
2375 Morse Avenue
Irvine, CA 29612
Tel. (949) 851-3053

b. Contact Person: Bonnie Bishop
Director, Regulatory Affairs and Quality Assurance
Tel. (949) 851-3053

c. Date Summary Prepared: June 18, 2004

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Inquiry™ AFocus™, Inquiry™ AFocus II™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter

b. Classification names: Catheter, Electrode Recording

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Irvine Biomedical, Inc.
Device:	Inquiry™ AFocus™ Steerable Electrophysiology Catheter
510(k):	K010471
Date Cleared:	June 6, 2001

Company:	Irvine Biomedical, Inc.
Device:	IBI-1100 Inquiry™ Steerable Electrophysiology Catheter System
510(k):	K961924
Date Cleared:	April 11, 1997

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The Inquiry™ AFocus™, Inquiry™ AFocus II™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter is a flexible, radiopaque catheter with a variable number of electrodes with the first electrode located at the distal tip and the other band electrodes following at predetermined distances. A connecting cable is used to connect the catheter to electrogram devices.

The catheter has a distal loop in a plane perpendicular to the catheter body. The circumferential shape or loop allows the electrophysiologist to record the potentials of cardiac structures without changing the position of the catheter. The catheter shaft and/or loop is steerable by manipulating the handle. The placement of the electrodes around the entire circumference of the distal loop also assists the electrophysiologist during fluoroscopy with visualization. The distal loop shape is easily straightened with the thumb and forefinger to facilitate insertion into sheaths and introducers. Once the catheter is extended beyond the sheath, the catheter resumes its pre-formed shape.

The device is supplied sterile and is intended for single use only.

5. **Statement of intended use:**

The Inquiry™ AFocus™, Inquiry™ AFocus II™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter is used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheter is designed to map the atrial regions of the heart.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The Inquiry™ AFocus™, Inquiry™ AFocus II™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter and its predicate devices are intended for electrogram recording and stimulation during electrophysiological studies. The modifications do not affect the intended use or scientific technology of the device, as embodied in the catheter.

7. **Brief summary of nonclinical tests and results:**

The test plan for the Inquiry™ AFocus™, Inquiry™ AFocus II™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter was based on the guidance document "Electrode Recording Catheter Preliminary Guidance, Draft Version", March 1995. Test results indicate reliable performance when the device is used in accordance with the Instructions for Use. The catheter does not raise new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2004

Irvine Biomedical, Inc.
c/o Ms. Bonnie Bishop
Director, Regulatory Affairs and Quality Assurance
2375 Morse Avenue
Irvine, CA 92614

Re: K042775
Trade Name: Inquiry™ AFocus™ Steerable Electrophysiology Catheter
Inquiry™ AFocusII™ Steerable Electrophysiology Catheter
Inquiry™ Optima™ Steerable Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II (two)
Product Code: DRF
Dated: October 1, 2004
Received: October 6, 2004

Dear Ms. Bishop:

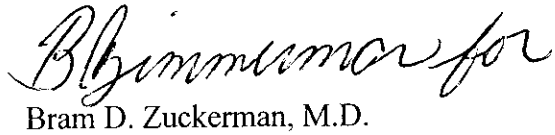
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042775

Indications for Use Statement

510(k) Number (if known): K042775

Device Name: Inquiry™ AFocus™ Steerable Electrophysiology Catheter
Inquiry™ AFocus II™ Steerable Electrophysiology Catheter
Inquiry™ Optima™ Steerable Electrophysiology Catheter

Indications for Use:

The Steerable Electrophysiology Catheter is used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheter is indicated for mapping the atrial regions of the heart.

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042775